TITLE

ENDOVASCULAR BALLOON GRAFT

CROSS REFERENCE TO RELATED APPLICATION

This application claims the benefit of and priority to U.S. Provisional Application No. 60/437,092 entitled "Morsi Balloon Graft" and filed December 30, 2002

BACKGROUND OF INVENTION

1. Field of Use

The invention pertains to a graft design that combines the minimal size and increased flexibility in its deliverable form which allows for successful navigation of torturous, stenotic blood vessels, aneurysms and other body passages with an in situ increase in size and rigidity, thus improving upon the current covered stent in treatment of various diseases such as atherosclerosis and aneurysms. The invention can be utilized in both the cerebral or peripheral circulatory system.

2. Prior Art

Inflatable devices for opening stenotic blood vessels are known. Devices such as angioplasty balloons, however, are unsuitable for permanent placement since the balloon component is fused to the catheter. Removal of the catheter will cause the collapse of the balloon. Further, the balloon itself may obstruct the lumen of the artery. Further, the procedure usually requires two *separate* steps; the first clearing of the occlusion and, second, the placement of a reinforcing stent with increased risk of embolization and the risk of restenosis. Currently metallic stents covered with a membrane are often installed as the second step.

Devices for treatment of aneurysms may not provide sufficient wall support or, alternatively, have material properties hindering their deployment within the affected portion of a vessel. Other devices may be subject to dislocation by the mechanics of fluid flow and pressure. Further, other devices of treating aneurysms, such as coils, are not suitable for certain types of aneurysms, e.g., wide neck or fusiform aneurysms. They may also be subject to incomplete olbitration of the aneurysm or coil compaction

which may result in re-growth of the aneurysm and future rupture. Devices that are of a braid type construction are subject to variations of the longitudinal length in relation to radial expansion.

SUMMARY OF INVENTION

The invention pertains to a method and apparatus for the repair of stenotic vessels utilizing an inflatable device that can open the occlusion with minimized occurrence of residue breaking free within the blood flow, thereby risking injury to another part of the body, while simultaneously creating a smooth interior walled lumen but with an undulating or corrugated outer wall surface to facilitate secure placement within the intended portion of the vessel. The device also can be moved into position while in a collapsed state, thereby minimizing disruption or irritation of the lumen, and subsequently inflated to create a substantially flexible but stiff walled shent capable of contouring to the shape of the lumen without collapse or buckling.

The device subject of the invention decreases the risk of distal embolization by providing a single system that performs both balloon angioplasty and delivery of the graft in a relatively easy fashion. The flexible nature of the device during deployment allows precise positioning and with no risk of shortening as the length of the graft remains fixed during expansion and deployment. In addition, the device subject of the invention can be retrievable and is compatible with MRI diagnostic testing.

The invention also pertains to a method and apparatus for repairing aneurysm vessels by providing a graft design that, when deployed across the aneurysm, will effectively exclude the aneurysm from circulation *and* reinforce the weak blood vessel wall. This minimizes possible re-growth or recanalization. It will be appreciated that the operation of the invention reinforces the blood vessel wall both at the location of the aneurysm and in the proximate surrounding area.

The method taught be the invention further decreases the time and cost of the procedure. The method further permits good visualization of the graft during and after deployment through the use of radio-opaque inflating materials. The device and method of the invention also decreases the risk of intimal hyperplasia and resenosis.

Other benefits of the invention will also become apparent to those skilled in the art and such advantages and benefits are included within the scope of this invention.

SUMMARY OF DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of the specification, illustrate preferred embodiments of the invention. These drawings, together with the general description of the invention given above and the detailed description of the preferred embodiments given below, serve to explain the principles of the invention.

Figure 1A illustrates the duel lumen catheter utilized to install the device.

Figure 1B illustrates a cross sectional view of the catheter.

Figure 1C illustrates a cross sectional view of the invention.

Figure 1D is a perspective view of the invention.

Figure 1E is an axial cross sectional view of the inflated device showing internal webbing.

Figure 1F is a circumferential cross sectional view of the inflated device.

Figure 2A illustrations the use of the catheter for inflating the invention.

Figure 2B illustrates a cross sectional view of the catheter.

Figure 2C illustrates a cross sectional view of the device during deployment.

Figure 3A, 3B & 3C illustrate the catheter and the invention in the process of inflation.

Figure 4A, 4B & 4C illustrate the catheter and invention after completion of the inflation step.

DETAILED DESCRIPTION OF INVENTION

The above general description and the following detailed description are merely illustrative of the subject invention and additional modes, advantages and particulars of this invention will be readily suggested to those skilled in the art without departing from the spirit and scope of the invention.

Figure 1A illustrates the system of the invention, being composed of a distal segment **1**, which represents the expandable graft and a proximal segment **2**, which

represents the delivery catheter. The catheter **2** has a double lumen shaft **3**. Figure 1B illustrates a cross sectional schematic of the catheter at a vector arrow **BB** in Figure 1A. As shown in Figures 1A and 1B, the larger lumen **5** has an aperture proximally **7**, and opens distally **8** into the lumen **18** of the distal segment that provides an artificial flow path for the body lumen. Through this lumen, a guiding wire (not shown) can be inserted to facilitate proper positioning of the graft at the desired location in the cerebral or peripheral circulatory system and also to maintain the elongated shape of the graft during insertion.

The smaller catheter lumen **6** has an aperture proximal **9** that can be attached to an inflating device. Distally it is attached to, and in fluid communication with, the fluid tight chambers **16** within segments **17A, 17B, 17C, 17D 17E** inside the graft **1** through a detachable check valve **10**.

Figure 1C is a cross sectional schematic view of the collapsed graft at vector arrow **CC** in Figure 1A. The graft is completely deflated and folded to a circumference **3A** equal to the diameter **3** of the catherter in Figure 1B. Figure 1C also illustrates the inner wall **13** of the graft, the outer wall surface **12**, folds **28** of the outer graft wall, the collapsed chambers **16** and the lumen **18** of the graft. The longitudinal orientation of the folds **28** of the graft is shown in one segment **17B** of Figure 1A.

The graft **1**, in its preferred embodiment is a double walled graft made of a bio-compatible, non-compliant non-porous material from a variety of suitable polymers, such as polyethylene, polyurethane, TFE, PTFE and ePTFE. In the preferred embodiment of the invention, the device, when inflated, forms a predetermined shape and size without becoming distorted. However, it will be appreciated that in other applications, a controlled elasticity of the device in one or more directions with inflation may be desirable. The double wall construction of the device is illustrated in Figures 1D, 1E and 1F discussed below.

In the preferred embodiment of the invention as illustrated in Figures 1D, 1E and 1F, the outer wall **12** is circumferentially **605** and longitudinally **690** larger than the inner wall **13**. This is particularly illustrated in Figure 1F, which also illustrates the internal support struts or webs **20** within the chamber **16**. Again, it is within these chambers that that the inflating fluid **21** is deployed. The construction of the inner and outer wall

described above allows the inner wall **13** to retain a relatively smooth surface facilitating unimpeded blood flow and the outer wall surface **13** to form a corrugated surface facilitating the shent device to adhere to the vessel wall. These contrasting surfaces **12 13** are illustrated in Figure 1D.

The two walls **12 13** are completely sealed together both distally and proximally to form the fluid tight chambers **16** that is only attached to, and in fluid communication with, the smaller lumen of the delivery catheter through a detachable check valve **10**. Each graft segment **17** comprising the invention contains a fluid tight chamber **16** interconnected by pathways **19** and through which the inflating fluid **21** is conveyed.

The walls are also interconnected by network of integral radially oriented support or retention webs. The radial **680** orientation of the web structure **20** is illustrated in Figures 1E and 1F. The radial oriented web network is preferably of equal length through out the whole length of the individual chamber **16** except at the periphery of the chamber where the web structure tapers in length toward the non-expansive junction. The graft design allows a significant portion of the graft wall to be stiffened with the fluid, thereby providing desired strength from collapse of the body lumen.

Figures 1D and 1F further illustrate the inner and outer walls to be circumferentially joined together at multiple restricted or non-expandable junctures **14**. These fused juncture may be spaced equally throughout the length of the graft 1, thus dividing the inner chamber of the graft into the multiple smaller fluid tight chambers **16** which may of equal linked segments **17A, 1B, 17C, 17D 17E**. Each chamber is connected with, and in fluid communication with, the adjacent chamber through one of more valves or holes **19** located in the fused junctures. These fluid communication channels may, or may not, have a common longitudinal orientation. (Figure 1D illustrates an embodiment having common longitudinal orientation.)

Figure 1D illustrates the fully deployed graft. The outward radial expansion of the individual segments **17A, 1B, 17C, 17D 17E** has been exaggerated for clarity of illustration. Also illustrated are vector arrows or lines showing the longitudinal **690** orientation, radial **680** orientation, and circumferential **605** orientation of the invention as described in this specification.

Figure 1E illustrates an axial cross section of a chamber of the invention, illustrating the multiple webs **20** that may be used to join the two walls together throughout the circumference of the chamber. This configuration ensures that the graft thoroughly inflates to a pre-selected shape without distortion; with a smooth inner surface, a thin film-like lumen, and a corrugated outer surface, which will anchor the graft to the inside of the blood vessel and prevents the drag force of the flowing blood through the graft form displacing the graft.

Figure 1F illustrates a longitudinally oriented cross section of a chamber showing the tapered length of the web structure **20**, the fused juncture **14** of the inner **13** and outer **12** wall. It will be appreciated that the inflation/stiffing fluid **21** fills the interstitial space

Figure 1F also illustrates the junctures **14** to be very small in width (about one millimeter) **29**. They serve both as conduit that connects the adjacent chambers **16** through multiple holes **19** within, and as bending areas (as they do not expand or pressurized when the graft is fully inflated) thus giving the graft some flexibility between the fully inflated segments **17A, 1B, 17C, 17D 17E**; allowing it to conform to the shape of the blood vessel without the risk of kinking or distortion. They also provide a space on its outer surface for neointimal growth that will further help anchoring and stabilizing the graft. It will be appreciated that the design selection of the segments and junctures may facilitate deployment of the device within varying vessel diameters, tissue structure or architecture. In other embodiments, side fenestrations may be created at selected locations of the invention to allow deployment of across bifurcating blood vessels without compromising blood flood.

It will be further appreciated that the material may selectively include fiber reinforcement, particularly in applications where the device may be subjected to repetitively varying pressures. Such fiber may be presumably installed in a circumferential orientation, but other designs may be found advantageous.

Figures 1A and 1C illustrate the graft at the start of deployment and during that portion of the procedure for placing the graft in the selected location within the body lumen. The graft is completely deflated and evacuated from any air and folded throughout its length in longitudinal folds **28** around the lumen **18** in a radial fashion to a

circumference **3A** approximating the circumference **3** of the delivery catheter **2**, illustrated in Figure 1B. A very thin sheath (not shown) can cover the outer surface of the graft; alternatively, the edges **28** of the longitudinal folds can be loosely adherent together to help maintain the longitudinal shape and smooth outer surface of the graft during insertion.

The proximal end of the graft is tightly packed into a groove (not shown) on the opposing end of the delivery catheter wall.

Figures 2A, 2C, 3A, 3C 4A and 4C sequentially illustrated the deployment of the graft in a selected location by the addition of a specified fluid **21** through the catheter **2**. The graft has an elongated cylindrical shape when fully inflated and pressurized and has a lumen **18** therein, which provides an artificial flow path for the body lumen (not shown). It is composed of an outer wall **12**, and an inner wall **13**, wherein the filler material **21** is provided between the two walls to inflate the graft into its predetermined inflated size and shape. Also illustrated is the fluid communication pathway **19** existing between segments **17A, 1B, 17C, 17D 17E**. The fluid can be a curable resin system, thereby providing additional stiffening reinforcement to the vessel walls. In addition, the fluid system may also adhere to the inner walls of each segment comprising the invention.

Figures 2, 3, & 4 explain the method of the invention. Using fixed radio-opaque markers at both ends of the graft **24**, the graft can be perfectly positioned at the desired location within the human lumen (not shown). The graft is deployed by injecting a fluid or gel material of contrast media, monomer, or uncrossed polymer through a pressure monitoring inflation device attached to the proximal end of the small lumen of the delivery catheter, which gradually fills the small catheter lumen **21**, and flows across the detachable valve into the chambers of the graft in a successive fashion **22**. The fluid may be a curable polymer resin system.

As the chambers of the graft fill gradually, the graft starts to unfold **23** and expand **25** in a radial fashion outward. After the graft expands to its predetermined shape and size **26**, a slight increase in the amount of the injected material will lead to increased pressure inside the graft, and exert a sufficient radial force outward, thus becoming axially and sealingly fixed to the inside of the blood vessel.

The graft can then be detached from the delivery catheter **27** through the detachable valve leaving the graft fully expanded and pressurized. This graft design functions as a covert stent graft for treating diseases such as atherosclerosis and aneurysms.

This specification is to be construed as illustrative only and is for the purpose of teaching those skilled in the art the manner of carrying out the invention. It is to be understood that the forms of the invention herein shown and describe are to be taken as the presently preferred embodiments. As already stated, various changes may be made in the shape, size and arrangement of components or adjustments made in the steps of the method without departing from the scope of this invention. For example, equivalent elements may be substituted for those illustrated and described herein and certain features of the invention may be utilized independently of the use of other features, all as would be apparent to one skilled in the art after having the benefit of this description of the invention.

Further modifications and alternative embodiments of this invention will be apparent to those skilled in the art in view of this specification.